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10/587,264

09/11/2006

Megumi Takeuchi

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08/04/2009

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EXAMINER

PIHONAK, SARAH

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/587,264 | Applicant(s) TAKEUCHI ET AL. | |
| | Examiner SARAH PIHONAK | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

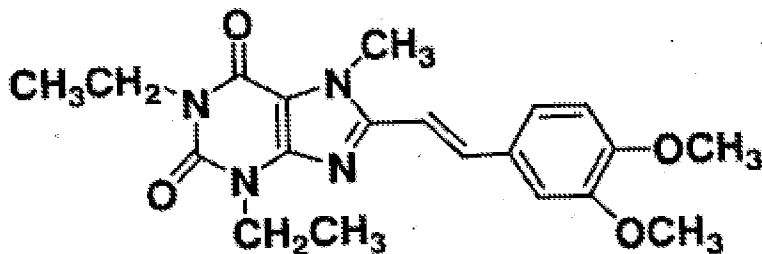
This application is a 371(national stage application) of PCT/JP05/01634, filed on 1/28/2005.

Priority

This application is a 371 of PCT/JP05/01634, filed on 1/28/2005, and claims foreign priority to Application No. 2004-019496, filed on 1/28/2004. A certified copy of the foreign priority application has been received. Therefore, the effective US filing date of the instant application is 1/28/2005, and priority date given to the instant claims is 1/28/2004.

Response to Restriction Requirement

1. Applicant's election of the invention of Group II, claims 6-7, in the reply filed on 5/8/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In the reply filed on 5/8/2009, the Applicant's elected the compound, Istradefylline, which is shown below:



2. Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Election was made **without** traverse in the reply filed on 5/8/2009. In the reply filed on 5/8/2009, Applicants cancelled claim 7 and added new claim 8. Claim 8 is withdrawn from consideration, as it is drawn to a composition and is a nonelected invention. Accordingly, this restriction requirement is made **FINAL**.

3. Claim 6 was examined.

4. Claim 6 is rejected.

Claim Rejection-35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

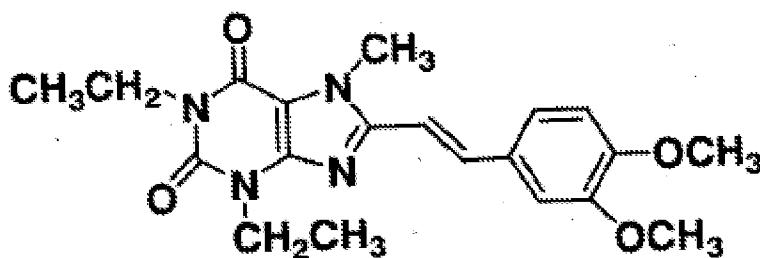
7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et. al., *J. Neuroscience*, **21**, pp. RC143 (1-6), in view of Strong, *J. Pharmacy and Pharmacology*, **49**, p. 1260.

9. Instant claim 6 is drawn to a method of treating migraine which comprises administration of the elected compound, Istradefylline, shown below:



Chen et. al. teaches that caffeine and Istradefylline or 8-[(1E)-2-(3,4-dimethoxyphenyl)ethenyl-3,7-dihydro-7-methyl-1H-purine, 2,6-dione, which is also known commercially as KW 6002, are both antagonists of the adenosine A₂ receptor (Abstract; p. 1, second paragraph; p. 3, last paragraph). Chen et. al. does not teach that caffeine or Istradefylline are effective for migraine treatment.

Strong teaches that compositions comprised of caffeine are especially effective in reducing migraine, in comparison to other analgesics (p. 1260, paragraphs 2-3).

Strong teaches that low doses of caffeine were successful in reducing migraines, and

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that caffeine alone was also effective (p. 1260, paragraphs 3 and last 3 paragraphs). It was also noted that caffeine is a vasoconstrictor (p. 1260, last sentence).

Chen et. al. teaches that both caffeine and Istradefylline are inhibitors of the adenosine A₂ receptor. Strong teaches that compositions comprised of caffeine are effective in reducing the incidence of migraines, in comparison to other analgesics.

It would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to administer Istradefylline to treat migraines, as the prior art teaches that caffeine and Istradefylline are both inhibitors of the adenosine A₂ receptor, and caffeine is effective in reducing migraines. Istradefylline, like caffeine, is a xanthine derivative. Caffeine, as an inhibitor of the adenosine A₂ receptor, has vasoconstricting activity, which is known to be effective in migraine treatment. As Istradefylline is also a xanthine derivative and a potent inhibitor of the adenosine A₂ receptor, this compound would also have been expected to act as a vasoconstrictor. Therefore, as both caffeine and Istradefylline are both xanthine derivatives and inhibitors of the adenosine A₂ receptor, and it is taught by Strong that caffeine is effective for reducing migraines, one of ordinary skill in the art would have expected success in substituting Istradefylline for treating migraines in lieu of caffeine.

Information Disclosure Statement

10. The information disclosure statement (IDS) submitted on 10/25/2006 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1617